Louisiana Office of Public Health Laboratories	
Test Name	Antibody to Hepatitis C Virus EIA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86803
Synonyms	HCV Anti-HCV
Brief Description of Test	The ORTHO HCV ELISA Test System is used for the detection of antibody to hepatitis C virus (Anti-HCV) in human serum. The hepatitis C virus (HCV) is now known to be the causative agent for most, if not all, blood-borne non-A, non-B hepatitis.
Possible Results	Nonreactive Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	210 µL serum (does not allow for repeat testing)
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use. Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first

	and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens can be shipped refrigerated (2-8°C) or ambient (8-37°C) and can be stored for up to 7 days. For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Gross hemolysis, heat-treated specimens, improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	Specimens with absorbance values greater than or equal to the Cutoff value are considered initially reactive and should be retested in duplicate before final interpretation. Upon retesting an initially reactive specimen, the specimen is considered repeatedly reactive for antibody to HCV if either or both duplicate determination(s) is/are reactive, i.e. greater than or equal to the Cutoff Value. The presence of anti-HCV does not constitute a diagnosis of hepatitis C, but may be indicative of recent and/or past infection by hepatitis C virus. A nonreactive test result does not exclude the possibility of exposure to hepatitis C virus. Levels of anti-HCV may be undetectable in early infection.
Interfering Substances	Clear, nonhemolyzed specimens are preferred. However, no effect on reactivity was observed when specimens were treated with 50-200 mg/dL of hemoglobin and 194-1285 mg/dL of triglyceride. Do not use any heat-treated specimens.
References	ORTHO® HCV ELISA Test System Package Insert EVOLIS™ Operator Manual
Additional Information	None

Release Date	03/15/2016
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	